

Summary of Safety and Effectiveness Information

K070973

Sponsor: Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
(906) 226-4812
Contact: Jonathan M. Gilbert

Device Name: Quantum Spinal System

Classification Name: Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System and Pedicle Screw Spinal System, Class III.

Predicate Device: K041167 – Quantum Spinal System, K070551 – Quantum Spinal System, K052151 - Synthes Pangea Monoaxial System, K031175 - Synthes Click'X Monoaxial System

Intended Use: The Quantum Spinal System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2), posterior hook (T1 – L5), sacral/ilic screw fixation or as an anterolateral fixation system (T8 – L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Material: Materials used to manufacture the implants (titanium alloy) and instruments (medical grade stainless steel) of this system are in conformance with ASTM Standard Specifications.

Performance Data: Testing per recognized ASTM standards was presented.

Performance and SE Determination: Comparisons of device performance data, materials, indications and design/function to predicate devices were provided in making a determination of substantial equivalence.

JUL - 3 2007



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pioneer Surgical Technology
% Mr. Jonathan Gilbert
VP, Clinical and Regulatory Affairs
375 River Park Circle
Marquette, MI 49855

JUL - 3 2007

Re: K070973
Trade/Device Name: QUANTUM Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, KWQ, KWP, MNI, MNH
Dated: April 4, 2007
Received: April 6, 2007

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

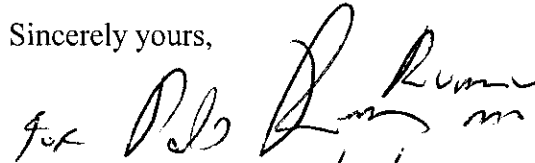
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson 7/3/07
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K070973

Device Name: Quantum Spinal System

Indications for Use: The Quantum Spinal System components are non-cervical spinal fixation devices intended for use as a pedicle screw system (T1 - S2), a posterior hook and sacral/iliac screw fixation system or as an anterolateral fixation system (T8 - L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K070973